

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

**H&H WHOLESALE, INC., and
DOOR TO DOOR MEDICAL SUPPLY,
INC.,**

Plaintiffs,

Case No. 05-70788

v.

HONORABLE DENISE PAGE HOOD

UNITED STATES OF AMERICA,

Defendant.

**MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN
PART PLAINTIFFS' MOTION FOR AN EVIDENTIARY HEARING, AND FOR
RETURN OF SEIZED PROPERTY**

I. INTRODUCTION

This matter is before the Court on Plaintiffs' Motion for an Evidentiary Hearing and for Return of Seized Property, filed July 23, 2005. The Government submitted its Response Brief on August 10, 2005. Plaintiffs replied on August 15, 2005.

On March 7, 2005, federal law enforcement agents executed a search warrant on Plaintiffs' place of business. The Government physically seized samples of blood glucose test strips ("BGTS"). The Office of In Vitro Diagnostic Device Evaluation and Safety, Health and Human Safety examined the BGTS samples to determine if they complied with the Food and Drug Cosmetic Act. The Government instructed Plaintiffs to not remove or distribute the remainder of the \$3.5 million worth of BGTS. The Government informed Plaintiffs that "certain BGTS labeled as 'Not for sale in the U.S.' or the equivalent were misbranded and/or adulterated and therefore could not

be sold in the United States.” (Gov’t’s Resp. at 1.) Plaintiff maintains “there is simply no difference whatsoever between those [BGTS] which the manufacturers choose to distribute domestically, and those which they choose to distribute outside of the United States (and which were seized from H&H).” (Pls.’ Mot. at 5) (internal quotation and citation omitted). For the reasons set forth below, the Court denies Plaintiffs’ Motion for an Evidentiary Hearing and grants in part and denies in part Plaintiffs’ Motion for Return of Seized Property.

II. STANDARD OF REVIEW

Fed. R. Crim. P. 41(g) states as follows:

A person aggrieved by an unlawful search and seizure of property or by the deprivation of property may move for the property’s return. The motion must be filed in the district where the property was seized. The court must receive evidence on any factual issue necessary to decide the motion. If it grants the motion, the court must return the property to the movant, but may impose reasonable conditions to protect access to the property and its use in later proceedings.

Once the movant makes out a *prima facie* case of lawful entitlement, the burden shifts to the government to show that “it has a legitimate reason to retain the property.” *United States v. Chambers*, 192 F.3d 374, 377 (3d Cir. 1999).

IV. APPLICABLE LAW & ANALYSIS

As an initial matter, the Government argues that because “[m]ost of the BGTS which are the subject of the instant motion were left on the premise [sic] of H&H Wholesale . . . the Court cannot order the return of property that was never seized.” (Gov’t’s Resp. at 1-2.) However, a “seizure” need not be a physical deprivation: “[a] ‘seizure’ of property occurs when there is some meaningful interference with an individual’s possessory interests in that property.” *United States v. Jacobsen*, 466 U.S. 109, 113 (1984). Clearly, the Government has imposed conditions upon Plaintiffs with respect to the BGTS amounting to “meaningful interference.”

The Government contends that the reason the BGTS have been seized is because federal regulators have deemed them to be misbranded and/or adulterated, or at least suspect as much. (Gov't's Resp. at 2.) Further, the BGTS are part of an ongoing Government investigation into possible criminal charges. (See Pls.' Reply at 2.) The Government claims it needs only the small number of BGTS in its physical possession for use in the criminal investigation. While it is unclear if the criminal investigation is ongoing, the Government clearly seized the BGTS for purposes of its criminal investigation. Plaintiffs forcefully contest the Government's assertions, and allege the prospect of irreparable harm should the BGTS not be returned to Plaintiffs. Plaintiffs allege the entire \$3.5 million of BGTS face spoilage – risking Plaintiffs' entire businesses as well. Plaintiffs ask the Court to hold an evidentiary hearing in order to determine whether the BGTS are actually misbranded and/or adulterated.

The Government asserts the May 2, 2005 Food and Drug Administration (“FDA”) letter prohibits the sale or other disposition of the seized items, although the Government claims it does not represent the FDA. Were the Court to order the return of the property seized under the lawful search warrant, the items may be subject to FDA detention, although Plaintiffs may question the form of that detention. The May 2, 2005 FDA letter can be construed as detention sufficient for Plaintiffs to appeal through the administrative procedure outlined in the Code of Federal Regulations. See 21 C.F.R. § 800.55(g). The question of whether the letter is a proper notice of administrative detention may also be appealable to the District Director. *Id.*

The May 2, 2005 FDA letter informs Plaintiffs of the following determinations: (1) the FDA seized the BGTS pursuant to the search warrant; (2) the FDA's Center for Devices and Radiological Health, Office of In Vitro Diagnostic Device Evaluation and Safety conducted tests showing the

BGTS are adulterated and misbranded; (3) the reasons for the finding of misbranding; (4) distribution of adulterated or misbranded items is unlawful; (5) the BGTS remain seized as part of an ongoing criminal investigation; and (6) Plaintiffs may not distribute, move, destroy, or alter the BGTS without the prior written approval of the FDA. The letter was signed by Michael E. Cleary, the FDA Special Agent in Charge.

For a valid administrative detention, 21 C.F.R. § 800.55(d) requires that a detention order must be in writing, signed by the authorized FDA representative having reason to believe the devices are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the location where the devices are found. 21 C.F.R. § 800.55(d)(1). Section 800.55(d) further mandates that a detention order shall state the period, reasons, location of the detention. 21 C.F.R. § 800.55(d)(3). Section 800.55(e) sets forth the requirements for approval of the detention order, while Section 800.55(f) relates to the proper labeling or marking of a detained device. Section 800.55(h)(3)(i) allows the FDA representative who issued the detention order, or another responsible district office official, to give written approval for the movement of the detained devices to prevent interference with a company's operations or harm to the devices themselves.

It is not clear to the Court that the FDA letter rises to the level of a proper detention order or notice thereof. Similarly, it is not clear that the Special Agent was acting with approval under the FDA or the United States Attorney's office relative to the search warrant.

Plaintiffs' recourse, according to the May 2, 2005 letter, is to contact Special Agent Paul Straughn. Plaintiffs assert this person has not been able to provide any recourse whatsoever to date. Plaintiffs also argue that because the letter derives from the search warrant – and not any administrative action – their recourse is with the United States Attorney's office. Plaintiffs have

indeed sought relief both in writing and during meetings with the United States Attorney's office, without success. It is not clear on whose authority the May 2, 2005 letter was issued, or even whether it has any force whatsoever. The Court remains uncertain as to whether the United States Attorney does not represent the FDA in this matter, considering the letter is seemingly expressly related to the search warrant.¹ The Court agrees that Plaintiffs seem to be in administrative limbo regarding the return of the BGTS. However, there is an administrative process by which to challenge dictates of the May 2, 2005 letter, and the merits thereof.

Plaintiffs have not cited any case law providing the Court with the authority to return seized property *during* a criminal investigation, regardless of the alleged irreparable harm. A criminal investigation strikes the Court as "a legitimate reason to retain the property." *Chambers*, 192 F.3d at 377.

Plaintiffs also cite no authority for the Court to conduct a hearing in an effort to determine if the seized items are misbranded and/or adulterated. As noted above, the Code of Federal Regulations addresses administrative detentions. See 21 C.F.R. § 800.55. The Code provides, "[t]his section sets forth the procedures for detention of medical devices intended for human use believed to be adulterated or misbranded." 21 C.F.R. § 800.55(a). The Code section also sets forth the proper procedure for the issuance of a detention order. 21 C.F.R. § 800.55(d). Though Plaintiffs dispute the propriety of the May 2, 2005 letter from the FDA barring Plaintiffs from the economic use of the BGTS, this Court is not the proper forum to challenge that action.² Plaintiffs argue that

¹ In fact, it has been through the assistance of Assistant United States Attorney William Soisson that Plaintiffs and the Court have more information regarding the administrative detention procedure.

² The FDA is not a party to the instant action.

such a result leaves them with no redress, however, without clear authority to direct the Government to return the BGTS to Plaintiffs free of any FDA limitation, the Court declines to do so.

Nonetheless, the Court orders the BGTS seized by the Government and no longer needed as a part of the criminal investigation be returned to Plaintiffs forthwith. Such property is “returned” subject to any lawful limitation or detention by the FDA.

Accordingly,

IT IS ORDERED that Plaintiffs’ Motion for an Evidentiary Hearing [**Docket No. 2, filed July 23, 2005**] is DENIED without prejudice.

IT IS FURTHER ORDERED that Plaintiffs’ Motion for Return of Seized Property [**Docket No. 2, filed July 23, 2005**] is GRANTED IN PART and DENIED IN PART.

IT IS FURTHER ORDERED that the BGTS seized by the Government and no longer needed as a part of the criminal investigation be returned to Plaintiffs forthwith. Such property remains subject to any *lawful* limitation or detention by the FDA.

s/ DENISE PAGE HOOD
Denise Page Hood
UNITED STATES DISTRICT JUDGE

DATED: August 26, 2005